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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/626,931

07/25/2003

Dean A. Klein

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EXAMINER

MEHTA, PARIKHA SOLANKI

ART UNIT

PAPER NUMBER

3737

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DELIVERY MODE

08/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/626,931	Applicant(s) KLEIN ET AL.	
	Examiner PARIKHA S. MEHTA	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,7,9,10,14-20,25,26,33-39,41-45,61,62 and 82-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,7,9,10,14-20,25,26,33-39,41-45,61,62 and 82-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/31/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 March 2008 has been entered.

Drawings

2. The drawings are objected to because the new drawings are not properly labeled as new sheets. It also appears that Applicant has renumbered the previous drawings without also submitting amendments to the Description section of the specification to update these new figure numbers. It is recommended that Applicant maintain Figure Nos. 1-5 as originally filed, and submit new Figures 1-5 as Figs. 6-11. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

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3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: Zirconium Oxide Marker and Method of Imaging Marked Tissue During Radiation Therapy.

Claim Objections

4. Claims 2, 3, 7, 9 and 10 are objected to because of the following informalities:

Claims 2, 3, 7, 9 and 10 fail to set forth one or more limitations that further define the steps of the claimed method. Claim 3 appears to be directed towards limitations for the end result of the method, which does not place any limitation on the manner in which the steps of the inventive method are performed.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2, 3, 7, 9, 10, 14-20, 25, 26, 33-39, 41-45, 61, 62 and 90-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (US Patent No. 6,394,965), previously made of record,

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hereinafter Klein ('965), in view of McCrory (US PG Pubs. No. 2001/0004395 A1), previously made of record, hereinafter McCrory ('395).

Regarding claims 2, 3, 7, 9, 10, 14-20, 25, 26, 33-39, 41-45, 61, 62 and 90, Klein ('965) teaches a method of implanting a plurality of carbon-coated zirconium oxide particles in a breast lesion, forming an image of the lesion with x-ray or MRI, and treating the lesion with radiation therapy based on the information shown in the image (col. 2 lines 10-40, col. 3 lines 35-41 & 51-65). The biopsy and progress monitoring of Klein ('965) (col. 3 lines 58-62, col. 10 lines 6-27) constitutes computer assisted diagnosis as is presently claimed. Klein ('965) teaches performing surgery based on the mammographic findings (col. 10 lines 28-34). Klein ('965) states that the carbon coating may comprise pyrolytic carbon, vitreous carbon or graphite (col. 2 lines 24-30). Klein ('965) teaches the microparticles to be of a major dimension between 100-1000 μm , which constitutes a dimension of between about 1000-3000 μm as is presently claimed.

Klein ('965) does not teach the method and apparatus for marking tissue with a single carbon-coated zirconium microparticle. It has previously been held that changes in size, shape or duplication/elimination of known parts and elements are all obvious and unpatentable over the prior art (Bd. Pat. App. & Inter. 1989); *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966); *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)). It is also well known in the art that a fiducial marker should be of sufficient shape and size to allow it to be easily visualized and distinguished from the tissue in which it is located. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the quantity of microparticles, and to have changed their shape in order to achieve the desired degree of distinguishability between the marker and tissue in order to yield a method of marking tissue with a single carbon-coated zirconium oxide particle, as such changes are neither new nor unexpected. Furthermore, such changes to the prior art method would require nothing more than routine experimentation, which has previously been held as an unpatentable advance in the art (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Klein ('965) does not teach forming a second image, nor does Klein ('965) teach registering first and second images to position a patient for radiation therapy. In the same field of endeavor, McCrory ('395) teaches multimodal image registration for locating a lesion over multiple radiation sessions (Abstract, claim 34). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Klein ('965) to perform the additional imaging step and image

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registration as taught by McCrory ('395) to achieve the claimed invention, as the combination of prior art steps and elements to yield predictable results is not considered a patentable advance in the art (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claim 91, Klein ('965) and McCrory ('395) substantially teach all features of the presently claimed method as previously discussed for claim 90, but neither reference teaches the marker to consist only of zirconium oxide. It would have been obvious to one of ordinary skill in the art at the time of invention to have used uncoated zirconium oxide marker in the method of Klein ('965) and McCrory ('395) in situations where marker biocompatibility is unnecessary, as omission of the coating would reduce the cost of the marker.

8. Claims 82-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein ('965).

Regarding claims 82-88, Klein ('965) teaches a plurality of carbon coated zirconium oxide particles having length of about 1000 microns, but does not teach an embodiment consisting of a single carbon coated zirconium oxide particle having one of a dog bone, bar bell, tubular, or helical shape. It has previously been held that changes in size, shape or duplication/elimination of known parts and elements are all obvious and unpatentable over the prior art (Bd. Pat. App. & Inter. 1989); *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966); *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)). It is also well known in the art that a fiducial marker should be of sufficient shape and size to allow it to be easily visualized and distinguished from the tissue in which it is located, as it would not otherwise be useful. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to have modified the quantity of microparticles, and to have changed their shape in order to achieve the desired degree of distinguishability between the marker and tissue in order to yield the presently claimed invention, as such changes are neither new nor unexpected. Furthermore, such changes to the prior art marker would require nothing more than routine experimentation, which has previously been held as an unpatentable advance in the art (*KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385).

Regarding claim 89, Klein ('965) substantially teaches the claimed marker as previously discussed for claim 82, but does not teach a marker that consists only of a zirconium oxide body, i.e. one which is not carbon-coated. It has previously been held that the mere elimination of an element from a known apparatus is not a patentable advance over the prior art (*Ex parte Wu*, 10 USPQ 2031 (Bd. Pat.

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App. & Inter. 1989); *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975)). Accordingly, it would have been obvious to one of ordinary skill in the art to have modified Klein ('965) to omit the carbon coating and thereby achieve the presently claimed invention.

Response to Arguments and Amendments

9. The declaration under 37 CFR 1.132 filed 31 March 2008 has been considered but the statements presented therein are moot in view of the new grounds of rejection presented herein, as necessitated by Applicant's amendments, also of 31 March 2008. Examiner also respectfully directs Applicant's attention to the fact that the declaration cites the incorrect patent application; in section 1, the application "10/626,131" and shorthand notation "'131'" appear where "10/626,931" and "'931'" should be cited.

10. Applicant's drawings filed 31 March 2008 are effective to overcome the previous drawing objection, which is hereby withdrawn. However, new objections to the drawings filed 31 March 2008 are presented herein.

11. Applicant's arguments with respect to claims 2, 3, 7, 9, 10, 14-20, 25, 26, 33-39, 41-45, 61, 62 and 82-91 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/

Primary Examiner, Art Unit 3737

/Parikha S Mehta/

Examiner, Art Unit 3737